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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,133	03/20/2001	Michael P. Vitek	5405.214	3028

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EXAMINER
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MONTANARI, DAVID A

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/744,133	<b>Applicant(s)</b> VITEK, MICHAEL P.	
	<b>Examiner</b> David Montanari	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants arguments filed in amendment on May 2, 2005 has been entered.
2. Claims 1, and 3-10 are examined in this office action.
3. The rejection of claims 1, and 3-10 under 35 U.S.C. 101, as lacking utility has been withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, and 3-10 remain rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for reasons present in the office action mailed 2/01/2005.

Claims 1, and 3-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a hemizygous transgenic mouse, wherein the mouse comprises an inactive endogenous iNOS gene and a transgene encoding a human iNOS gene methods of using the mouse in screening potential compounds for induction and treatment of disease.

However, the specification does not enable the claimed invention because at the time of filing the use of the claimed mouse and methods required undue experimentation without a predictable degree of success.

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Applicant's arguments filed 5/2/2005 have been fully considered but they are not persuasive. Applicants argue that the rejection of claims 1, and 3-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is obviated for the same reasons in the applicants arguments set forth in the 35 U.S.C. 101 rejection. The examiner notes that the applicant has not addressed the specific enablement issues set forth in the previous office action, and considers that applicant has no specific arguments with regard to the 35 U.S.C. 112, first paragraph rejection of claims 1, and 3-10. As stated in the previous office action, "the specification has not shown that the claimed mice have any phenotype or linkage to the claimed methods involving AD, MS, IBD, and RA" (2/1/05 OA, pg. 6 parag. 3 lines 5-7). Therefore given the reasons presented in the previous office action, one skilled in the art at the time of filing would require and undo amount of experimentation without a predictable degree of success to make and use the claimed mouse and methods.

Therefore for the reasons above and of record, the rejection is maintained.

No claims are allowed.

The examiner notes that given the current state of the art, a role for iNOS in Inflammatory Bowel Disease, Alzheimer's Disease, Multiple Sclerosis, and Rheumatoid Arthritis has been established post-filing. The examiner specifically notes the following references: Kolios G, Nitric oxide in inflammatory bowel disease: a universal messenger in an unsolved puzzle, 2004, Immunology, Vol. 113, pgs. 427-42, Hill KE, Inducible nitric oxide synthase in chronic active multiple sclerosis plaques: distribution, cellular expression, and association with myelin damage, 2004, J.

of Neuroimmunology, Vol. 151, pgs. 171-179, Miljkovic D, Inducible nitric oxide synthase activation by interleukin-17, 2004, Cytokine and Growth Factor Reviews, Vol. 15, pgs. 21-32, Fernandez-Vizarra P, Expression of nitric oxide system in clinically evaluated cases of Alzheimer's disease, 2004, Neurobiology of Disease, Vol. 15, pgs. 287-305. However, given the current art supporting a role of iNOS in Inflammatory Bowel Disease, Alzheimer's Disease, Multiple Sclerosis, and Rheumatoid Arthritis this does not overcome the enablement rejection of the claimed mouse comprising an inactive iNOS gene and a transgene encoding the human iNOS gene.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A handwritten signature in black ink, appearing to read 'mshukla', written over a horizontal line.

**RAM R. SHUKLA, PH.D.**  
**SUPERVISORY PATENT EXAMINER**